REMARKS

The Final Office Action dated June 6, 2007 has been carefully considered. Claims 1, 16, 30, 31, 33, 35, 41, 42 and 48 have been amended. Claims 4, 5, and 38-40 have been canceled. Claims 1, 7-39, 35, 36, 41, 42, and 47-49 are in this application.

Support for the amendment to claims 1, 16, 30, 31, 33, 35, 41, 42 and 48 is found through the specification and in particular on page 16, lines 4-29. No new matter has been entered.

A provisional double patenting rejection has been made of the pending claims in this application over claims 1, and 3-50 of co-pending U.S. Patent Application No. 10/376,736. Applicants submit herewith a terminal disclaimer for overcoming this rejection.

Claims 1, 33, 35, 36, 48 and 49 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants have included the step of delivering therapeutic agents as suggested by the Examiner.

The previously presented claims 1, 13-15, 17, 18, 21, 27, 29-33, 42, and 47 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,780,047 to Kamiya et al. Applicants traverse the rejection.

The present claims recite one or more of the cosmetic, dermatological, or pharmaceutical active ingredient encapsulated in nanospheres or microspheres dispersed in the polymeric matrix layer, the nanospheres or microspheres are formed of a hydrophobic material. There is no teaching or suggestion of encapsulating active ingredients in Kamiya et al. Further, the present claims recite the patch is substantially water-free.

In contrast, in Kamiya et al. the adhesive layer is formed of a water-soluble polymer and water. See Col. 4, line 60 to Col. 5, line 3. Accordingly, the water content of Kamiya et al. provides an adhesive layer. In Kamiya et al., when a protective sheet is not provided for attachment to the adhesive layer, the patch is directly packed with a package of an aluminum foil-laminated film. In contrast, the absence of water in the patch of the present invention provide a patch which is not tacky and can be transported without the use of special package. As described on page 17, lines 8-14, the patch of the present invention can be cut to a particular size for a particular application. In contrast, Kamiya et al. teach a patch already including an adhesive layer which would make the patch sticky and difficulat to cut. Moreover, Kamiya et al.

do not teach a patch that, upon wetting, becomes tacky to support adhesive application to the skin. Kamiya et al. is adhesive at the start due to an adhesive layer being composed of water rather than becoming tacky and adhesive after wetting. Thus, Kamiya et al. do not teach every limitation of the claims.

The previously presented claims 1, 9, 10, 12, 14, 15, 17, 18, 21-24, 27, 29-33, 42, 47 and 48 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,497,887 to Zecchino et al. Applicants traverse the rejection.

In contrast to the invention defined by the present claims, Zecchino et al. do not teach or suggest that one or more of the cosmetic, dermatological, or pharmaceutical active ingredients are encapsulated in nanospheres or microspheres dispersed in a polymeric matrix layer and that the nanospheres or microspheres are formed of a hydrophobic material and the matrix layer is substantially water-free. To the contrary, Zecchino et al. disclose a membrane formed of a slurry of water and gel-forming polymer which cannot dissolve in water or disintegrate because it is formed of cross-linked polymers (Abstract and Col. 2, lines 10-19). There is no teaching or suggestion that the patch is removed by rinsing. Rather, the patch dissolves and is rubbed into the skin. Accordingly, the patch is not removed by water. Thus, Zecchino et al. do not teach every limitation of the claims.

The previously presented claims 7, 8, and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,780,047 to Kamiya et al. in view of U.S. Patent Application Publication No. 2003/0027833 to Cleary et al. Applicants traverse the rejection.

The Examiner conceded that Kamiya et al. do not teach the specific antiseptics and antibiotics recited in claims 7, 8 and 10. The Examiner attempted to cure the defect by combining the teachings of Kamiya et al. and Cleary et al. However, as discussed above and incorporated herein, Kamiya et al. is further defective and in failing to teach that one or more of the cosmetic, dermatological, or pharmaceutical active ingredients are encapsulated in nanospheres or microspheres dispersed in a polymeric matrix layer and that the nanospheres or microspheres are formed of a hydrophobic material and the matrix layer is substantially water-free and in failing to teach a patch that becomes tacky after wetting so that the adhesive property of the tacky patch adheres the patch to the skin. Cleary et al. do not cure the defect

because it does not teach the missing limitation and furthermore because Cleary et al. teach two different embodiments that are both defective as to the limitations of the claims. One embodiment is a liquid or gel that forms a film only after application to the body, so this embodiment is outside the limitations of the claims. The other embodiment is multilayered, so this embodiment is outside the limitations of the claims. Since the combination of prior art references the Examiner proposed is nonetheless defective in failing to teach each of the limitations incorporated into the claims, no prima facie showing of obviousness has been presented and the claims are patentable over the prior art.

The previously presented claims 7 and 8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,497,887 Zecchino et al. in view of U.S. Patent Application Publication No. 2003/0027833 to Cleary et al. Applicants traverse the rejection.

The Examiner conceded that Zecchino et al. do not teach the specific antiseptics and antibiotics recited in claims 7 and 8. The Examiner attempted to cure the defect by combining Zecchino et al. with Cleary et al. However, as discussed above, and incorporated herein, Zecchino et al. is further defective in failing to teach that one or more of the cosmetic, dermatological, or pharmaceutical active ingredients are encapsulated in nanospheres or microspheres dispersed in a polymeric matrix layer and that the nanospheres or microspheres are formed of a hydrophobic material and the matrix layer is substantially water-free and that the polymeric matrix layer of the patch dissolves in water or disintegrates upon rinsing the patch with water. Zecchino et al. do not cure the defect because it does not teach the missing limitation and furthermore because Zecchino et al. teach two different embodiments that are both defective as to the limitations of the claims, as discussed above and incorporated herein. Since the combination of prior art references the Examiner proposed is nonetheless defective in failing to teach each of the limitations incorporated into the claims, no prima facie showing of obviousness has been presented and the claims are patentable over the prior art.

The previously presented claim 11 was rejected under 35 U.S.C. § 103(a) as being unpatentable over any of U.S. Patent No. 5,780,047 to Kamiya et al. or U.S. Patent No. 6,497,887 to Zecchino et al. Similarly claim 12 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya et al. in view of Zecchino et al. Similarly claim 13 was rejected

under 35 U.S.C. § 103(a) as being unpatentable over Zecchino et al. in view of Kamiya et al. Applicants traverse the rejections.

The Examiner conceded that neither of the prior art references teach the anti-inflammatory agents recited in claim 11. The Examiner rationalized that since the references disclosed that anti-inflammatory agents are suitable for delivery from the respective compositions, it was within the skill in the art to determine the particular agents in claim 11. The Examiner further conceded that Kamiya et al. failed to teach the antihistamine of claim 12 but stated that Zecchino et al. teach the antihistamine. The Examiner further conceded that Zecchino et al. failed to teach the menthol or capsaicin of claim 13 but stated that Kamiya et al. teaches the menthol or capsaicin. Notwithstanding the Examiner's argument, the various combinations of the two references still fail to disclose every limitation that is incorporated into claims 11, 12 or claim 13. The discussion above of the missing limitations is incorporated herein. Since the combination of prior art references is nonetheless defective in failing to teach a membrane having that one or more of the cosmetic, dermatological, or pharmaceutical active ingredients are encapsulated in nanospheres or microspheres dispersed in a polymeric matrix layer and that the nanospheres or microspheres are formed of a hydrophobic material and the matrix layer is substantially water-free; the polymeric matrix layer of the patch that dissolves in water or disintegrates upon rinsing the patch with water; or a patch that becomes tacky after wetting, so that the adhesive property of the tacky patch adheres the patch to the skin, no prima facie showing of obviousness has been presented and the claims are patentable over the prior art.

The previously presented claims 9, 19, 20, 22-24, 26, 35, 36 and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,780,047 to Kamiya et al. in view of U.S. Patent Application Publication No. 2001/0007671 to Gueret. Applicants traverse the rejection.

The Examiner conceded that Kamiya et al. fail to teach the salicylic acid as claimed in claim 9, the transparent polymeric film as claimed in claim 19, the colored film as claimed in claim 20, the cosmetics claimed in claims 22-24, the effervescent claimed in claim 26, or the period of applying the film as claimed in claims 35, and 36. The Examiner attempted to cure the defect by combining the teachings of Kamiya et al. and Gueret. However, as discussed above and incorporated

herein, Kamiya et al. is further defective in failing to teach that one or more of the cosmetic, dermatological, or pharmaceutical active ingredients are encapsulated in nanospheres or microspheres dispersed in a polymeric matrix layer and that the nanospheres or microspheres are formed of a hydrophobic material and the matrix layer is substantially water-free and a patch that becomes tacky after wetting, so that the adhesive property of the tacky patch adheres the patch to the skin. Gueret does not cure the defect because it does not teach the missing limitations. For this reason, alone, no prima facie showing of obviousness has been presented and the claims are patentable over the prior art.

The previously presented claims 19, 20, 26, 35 and 36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,497,887 to Zecchino et al. in view of U.S. Patent Application Publication No. 2001/0007671 to Gueret. Applicants traverse the rejection.

The Examiner conceded that Zecchino et al. fail to teach the transparent polymeric film as claimed in claim 19, the colored film as claimed in claim 20, the effervescent as claimed in claim 26, or the period of applying the film as claimed in claims 35 and 36. The Examiner stated that these are all taught in the patch of Gueret. However, as discussed above, and incorporated herein, Zecchino et al. is further defective in failing to teach that one or more of the cosmetic, dermatological, or pharmaceutical active ingredients are encapsulated in nanospheres or microspheres dispersed in a polymeric matrix layer and that the nanospheres or microspheres are formed of a hydrophobic material and the matrix layer is substantially water-free and that the polymeric matrix layer of the patch dissolves in water or disintegrates upon rinsing the patch with water. Gueret which teaches a patch that is a hydrophilic gelling system that retains water, does not cure the defect. Since the proposed combination does not teach each of the limitations incorporated into these claims, no prima facie showing of obviousness has been presented and the claims are patentable over the prior art.

The previously presented claims 25 and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over any of U.S. Patent No. 5,780,047 to Kamiya et al. or U.S. Patent No. 6,497,887 to Zecchino et al. in view of U.S. Patent No. 6,419,935 to Gueret ("Gueret '935"). Applicants traverse the rejection.

The Examiner conceded that Kamiya et al. and Zecchino et al. fail to teach dihydroxyacetone as in claim 25 or the size of the film as in claim 28. The Examiner stated that Gueret '935 teaches these aspects and that it would have been obvious to combine the teachings of either Kamiya et al. or Zecchino et al. with that of Gueret '935. Notwithstanding the Examiner's argument, the various combinations of references still fail to disclose every limitation that is incorporated into claims 25 or claim 28. The discussion above of the missing limitations is incorporated herein. Since the combination of prior art references is nonetheless defective in failing to teach each of the limitations incorporated into the claims, no prima facie showing of obviousness has been presented and the claims are patentable over the prior art.

The previously presented claims 16 and 38-41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over any of U.S. Patent No. 5,780,047 to Kamiya et al. or U.S. Patent No. 6,497,887 to Zecchino et al., each in view of U.S. Patent No. 5,667,798 to Royds et al. Applicants traverse the rejection.

The defects in Kamiya et al. and Zecchino et al. have been discussed above and are incorporated herein. The Examiner conceded that those two references failed to teach microencapsulation of active ingredients as recited in claims 16, 38, 39, and 41, or microencapsulation in hydrophobic microcapsules as recited in claim 40. As discussed above and incorporated herein, Kamiya et al. is further defective in failing to teach a patch that one or more of the cosmetic, dermatological, or pharmaceutical active ingredients are encapsulated in nanospheres or microspheres dispersed in a polymeric matrix layer and that the nanospheres or microspheres are formed of a hydrophobic material and the matrix layer is substantially water-free and that becomes tacky after wetting, so that the adhesive property of the tacky patch adheres the patch to the skin. Royds et al. do not cure the defect because it does not teach the missing limitation and in fact teaches an additional layer containing adhesive (Col. 4, lines 47-53). As discussed above and incorporated herein, Zecchino et al. is further defective in failing to teach the polymeric matrix layer of the patch dissolves in water or disintegrates upon rinsing the patch with water. Royds et al. do not teach the missing limitation. Further, Royds et al. is directed to microcapsules formed of an active coating material. However, Royds et al. do not teach or suggest nanospheres or microspheres formed of a hydrophobic material. The

microspheres of the present invention provide release of the active from a hydrophobic material to provide a controlled release system. In contrast, Royds et al. is directed to coating which does not provide the same release characteristic. Therefore, the combinations the Examiner has proposed fail to teach each of the limitations incorporated into claims 16 and 38-41, so no prima facie showing of obviousness has been made and the claims are patentable over the prior art.

In view of all the rebuttal argument presented above, Applicants respectfully request that all the rejections for obviousness be reconsidered and withdrawn.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should she believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

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Diane Dunn McKay, Esq.
Reg. No. 34,586
Attorney for Applicants

MATHEWS, SHEPHERD, McKAY & BRUNEAU, P.A.
29 Thanet Road, Suite 201
Princeton, NJ 08540
Tel: 609 924 8555
Fax: 609 924 3036